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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/744,169	04/19/2001	Theresa Ann Jeary	P24,622 USA	3922

7590

04/25/2002

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 04/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/744,169	<b>Applicant(s)</b> JEARY ET AL.	
	<b>Examiner</b> Susan Tran	<b>Art Unit</b> 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-5 and 10-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-5 and 10-34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:  
         1. ☒ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____.  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

Receipt is acknowledged of applicant's Request for Extension of Time filed 04/19/01, Declaration filed 04/19/01, and Preliminary Amendments A and B filed 04/10/01.

#### ***Specification***

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

#### ***Response to Amendment***

The Amendments filed 04/10/01 are confusing. Amendment A, applicant requested to cancel claims 6-9, however, Amendment B, in page 9, applicant indicated that "claims 6 to 19 having been cancelled". Further clarification is requested.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4, 5, 10-24, and 28-347 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite because the structure of the claim is poor and confusing. If a major proportion of the coating membrane is water insoluble, it is unclear why the minor proportion of water soluble polymer is "optional"? Furthermore, what is the weight ratio

of said water insoluble and water soluble in the coating membrane? The phrasing "the ratio of said water insoluble polymer to said water soluble polymer, when said water soluble polymer is present, being effective to permit a SSRI release rate which allows controlled release of SSRI over a period of not less than about 12 hours following oral administration" is confusing. Further clarification is suggested.

Claims 10 and 12-19 are indefinite because they depend on the cancelled claims. Correction is requested.

Claim 11 is indefinite if the use of the phrase "substantially as hereinbefore described and exemplified". It is unclear as to what is being claimed? Further clarification is requested?

Claims 10, 15-17, 23, 24, 28-30 are rejected in the use of the phrase "substantially corresponds" because the term "substantially" is a relative term which renders the claim indefinite. The term "substantially" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claims 19, 33, and 34 are indefinite in the use of the phrase "other condition". The term "other" is vague because the metes and bounds of the patent protection are unascertainable. It is unclear if "other condition" is part of the claims or just exemplify. Correction is suggested.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 11-14, 19-22, 25-27, and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Landry et al. US 6,080,736, and Stark et al. US 6,066,339.

Landry teaches methods and compositions for treating and preventing anxiety and anxiety disorders comprising slow or controlled release pharmaceutical formulation suitable for oral administration, such as multi-layer coatings, microparticles, microspheres, osmotic system, or polymer matrices (column 17, lines 15 through column 18, lines 1-58). The composition comprising antidepressant, such as fluvoxamine as active agent; stabilizer; and excipient (column 19, lines 1-28; and claim 15).

Although Landry is silent as to the teaching of the rate-controlled coating, Landry teaches slow/controlled release formulation in the form of multi-layer coating, microspheres or microparticle.

Stark teaches oral multiparticulate formulation comprising drug core being coated with rate-controlling polymer, such as ammonia methacrylate copolymers (column 2, lines 58-65). The formulation further comprising an immediate release coating applied onto the rate-controlling polymer coat, and/or at least two populations of sustained release particles having different in vitro dissolution profiles (column 3, lines 13-53).

Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Landry's multi-layer coating formulation using the rate-controlling coating in view of the teaching of Stark because the references teach the advantageous result of slow/controlled release formulation. The expected result would be a slow/controlled release formulation containing SSRI compound, which is suitable to provide effective plasma levels of drug over at least 24 hours.

Claims 1-5, 11-14, 20-22, 25-27, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner et al. US 4,851,228, in view of Stark et al. US 6,066,339.

Zentner teaches multiparticulate controlled delivery system comprising active core coated with rate controlling water insoluble call (column 2, lines 57 through column 3, lines 1-10; column 10, lines 59 through column 11, lines 1-51). The active agent can be one or mixture of drugs, such as morphine, codeine, amiflamine, trazedone, doxepin, or fluvoxamine (column 12, lines 49 through column 14, lines 1-14).

Zentner is silent as to the teaching of the specific rate-controlled coating as claimed in claims 5 and 32.

Stark teaches oral multiparticulate formulation comprising drug core being coated with rate-controlling polymer, such as ammonia methacrylate copolymers (column 2, lines 58-65). Thus, it would have been prima facie obvious for one of ordinary skill in the art to modify Zentner's multiparticulate formulation using ammonia methacrylate copolymers as the rate-controlling coating in view of the teaching of Stark. The reason

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for this modification is to obtain a multiparticulate formulation from the controlled release of a drug to an environment of use. The expected result would be a slow/controlled release formulation containing antidepressant drug having prolonged release rate.

Claims 10, 13-17, 23, 24, and 28-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zentner et al. US 4,851,228, in view of Stark et al. US 6,066,339.

Zentner and Stark are relied upon for the reasons stated above. Although the references do not teach the claimed release profile, Stark teaches similar release profile (table in column 15, lines 40-50). Hence, it would have been obvious for one of ordinary skill in the art to, by routine experimentation determine a suitable release rate useful to deliver SSRI compound.

#### ***Pertinent Arts***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. James, Chungi et al., Midha et al., Hettche, and Arora et al. are cited as being of interest for the teaching of controlled release formulation comprising SSRI.

#### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Tran whose telephone number is (703) 306-5816. The examiner can normally be reached on Monday through Thursday from 6:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0193.

  
THURMAN K. PAGE  
SUPERVISORY/PATENT EXAMINER  
TECHNOLOGY CENTER 1600